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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Takeo TANAAMI et al.**

Art Unit: **1797**

Application Number: **10/716,417**

Examiner: **Nathan Andrew Bowers**

Filed: **November 20, 2003**

Confirmation No.: **6545**

For: **BIOCHIP CARTRIDGE**

Attorney Docket Number: **032106**

Customer Number: **38834**

REPLY BRIEF

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

November 20, 2008

Sir:

In response to the Examiner's Answer mailed October 1, 2008, the following is the Appellant's Reply Brief.

REMARKS

- I. **The position in the Examiner's Answer is either a new ground of rejection, or a recycling of a ground of rejection previously withdrawn by the Examiner.**

Throughout prosecution, Appellants have argued that the proposed modification of Christian would change the apparatus from the "parallel" apparatus to a hybrid "parallel/series" apparatus. However, in the Examiner's Answer, it is stated that "the proposition of modifying Christian to create a "series" arrangement has always been advanced – never a "parallel/series" configuration." Examiner's Answer, page 13, lines 6-8. Appellants respectfully submit that this

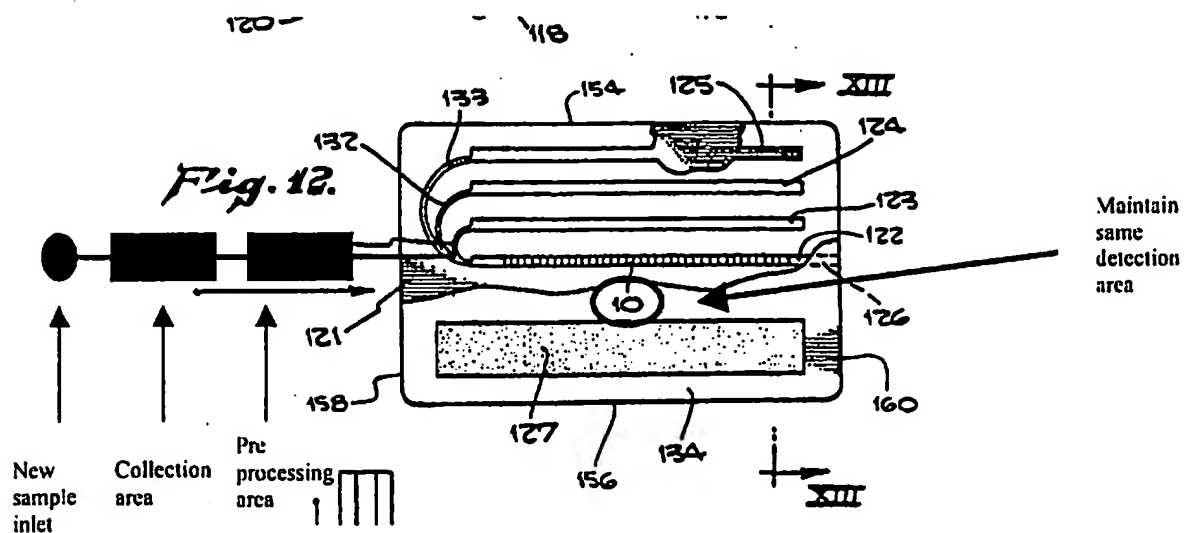
is inaccurate, and the proposed creation of a “series” arrangement is either a new ground of rejection, or a recycling of the grounds of rejection in the August 1, 2006 Office Action, which was subsequently withdrawn by the Examiner.

In the August 1, 2006 Office Action, the Examiner rejected the claims based on the combination of Christian, Schembri and either Schipelsky or the Admitted Prior Art (APA), arguing that “it would have been obvious to alter the arrangement of the channels and chambers in the apparatus disclosed by Christian in order to ensure that the biopolymers and biopolymer solutions are transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time differentiated manner.” August 1, 2006 Office Action, page 4, lines 7-10. In response to this rejection, Appellants argued that proposed modification of Christian would teach away from the proposed combination of cited art, since the proposed modification would remove Christian’s ability to selectively transfer solutions into a detection area. December 1, 2006 Amendment, page 10, lines 7-18.

On February 5, 2007, Appellants’ Representative and the Examiner conducted a telephone interview to discuss the rejection pending at that time. In the Applicants’ Statement of the Substance of the Interview dated February 20, 2007, Appellants stated that “[t]he Examiner argued that it would have been obvious to add an additional chamber to Christian, such that the biopolymers moved sequentially like in the APA.” Statement of the Substance of the Interview, page 2, lines 3-4 (emphasis added).

On March 7, 2007, the Examiner issued a non-final Office Action withdrawing the rejections involving Schipelsky and provided a new rejection. The Examiner at no time refuted

or clarified Appellants' comment in the Statement of the Substance of the Interview that it was the Examiner's position that it would have been obvious to add an additional chamber to Christian, thus creating a "parallel/series" apparatus. On the contrary, the Examiner stated that "[o]ne would have been motivated to modify the existing structure of Christian in order to provide a new sample inlet port, collection area and preprocessing area while maintaining the existing wash chambers disclosed by Christian." March 7, 2007 Office Action, page 12, lines 16-18 (emphasis added). Then, the Examiner provided the following illustration:



Additionally, in the Amendment filed on August 30, 2007, Appellants argued that the configuration in the March 7, 2007 Office Action would lead to contamination of solutions, since solution from the proposed new sample inlet/collection area/preprocessing area could inadvertently flow into wash chambers 123 and 125 and solution chamber 124, in addition to, or instead of, flowing into the microarray rod 10/detection chamber 122. Similarly, Appellants argued that solutions from the wash chamber 123 and 125 and solution chamber 124 could

inadvertently flow into the preprocessing area in addition to, or instead of, flowing into the microarray rod 10/detection chamber 122. Thus, Appellants argued that contamination would likely result in the modification proposed in the March 7, 2007 Office Action.

In the Final Office Action dated November 13, 2007, the Examiner had an opportunity to clarify or change the illustration of the proposed modification. The Examiner declined to do this. In the November 13, 2007 Office Action, the text of the rejection appears to be a word-for-word replica of the rejection in the March 7, 2007 Office Action. There is no explicit or implicit modification of the Examiner's position with respect to the proposed modification. In the November 13, 2007 Office Action, the Examiner made no comment about removing the wash chambers 123 and 125 and the solution chamber 124. In fact, the November 13, 2007 Final Office Action retained the position that the new sample inlet/collection area/preprocessing area should be provided in addition to the detection chamber 122, the wash chambers 123 and 125 and the solution chamber 124. Specifically, the Examiner stated:

Based on this figure, it does seem like it would be possible for sample solution to be accidentally diverted into the wash chambers. However, it is important to remember that this figure was created simply to further describe the serial flow pattern generally without showing every technical feature....[O]ne of ordinary skill in the art would recognize how to redesign the apparatus of Christian to ensure that the sample is not needlessly moved into the wash chambers. November 13, 2007 Office Action, page 11, line 18 to page 12, line 5.

In other words, the Examiner alleged that one having ordinary skill in the art would have known how to resolve this contamination problem by adding other technical features. In the November 13, 2007 Final Office Action, the Examiner did not argue that one having ordinary skill in the art

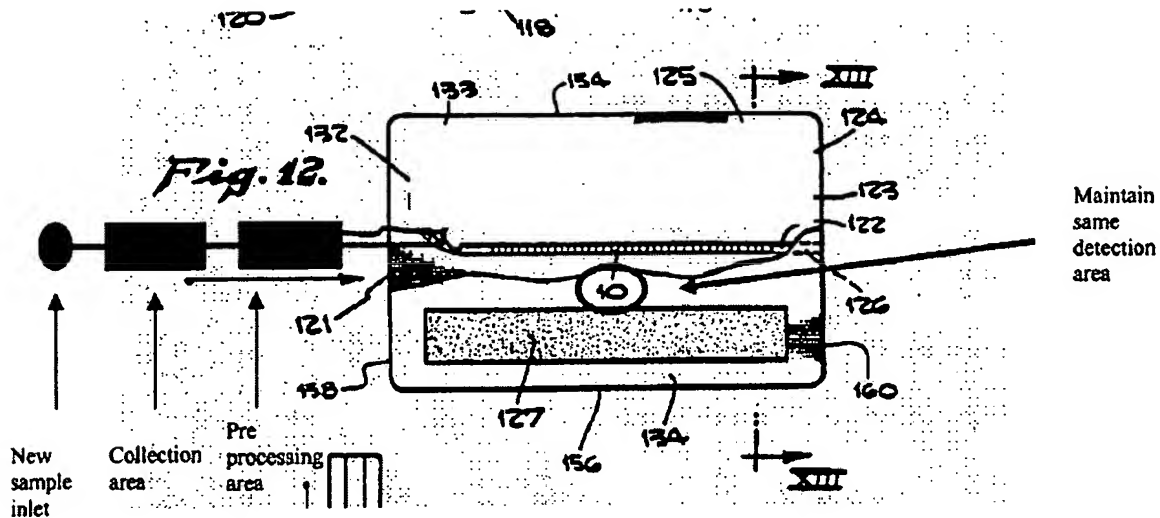
would have removed the wash chambers and solution chamber which the Examiner now regards as “obsolete and unnecessary.”

The Examiner also failed to raise this new interpretation of the prior art in the Advisory Action dated May 27, 2008. In this Advisory Action, the Examiner stated that:

Applicant should concentrate on the cited prior art teachings, and should not focus primarily on the March 7 illustration. That illustration was created as a courtesy in order to attempt to better explain the proposed modification through a visual representation. However, the illustration was generated using the only tools available – crude Microsoft office autosshapes – and should be disregarded where it conflicts with the text of the rejection and the teachings of the APA, Wilding and Anderson. May 27, 2008 Advisory Action, continuation sheet, lines 20-25.

Again, the Examiner did not retract or revise the substance of the March 7, 2007 illustration. While it is agreed that the cited prior art teachings are the focus of the pending rejection, the illustration provided serves to clarify the associated problems with the alleged combination of cited art. Appellants reiterate that the crudeness of the drawing is not at issue, and is not germane to the fact that the combination of references would result in a device which changes the device from a “parallel” device to a “series/parallel” device.

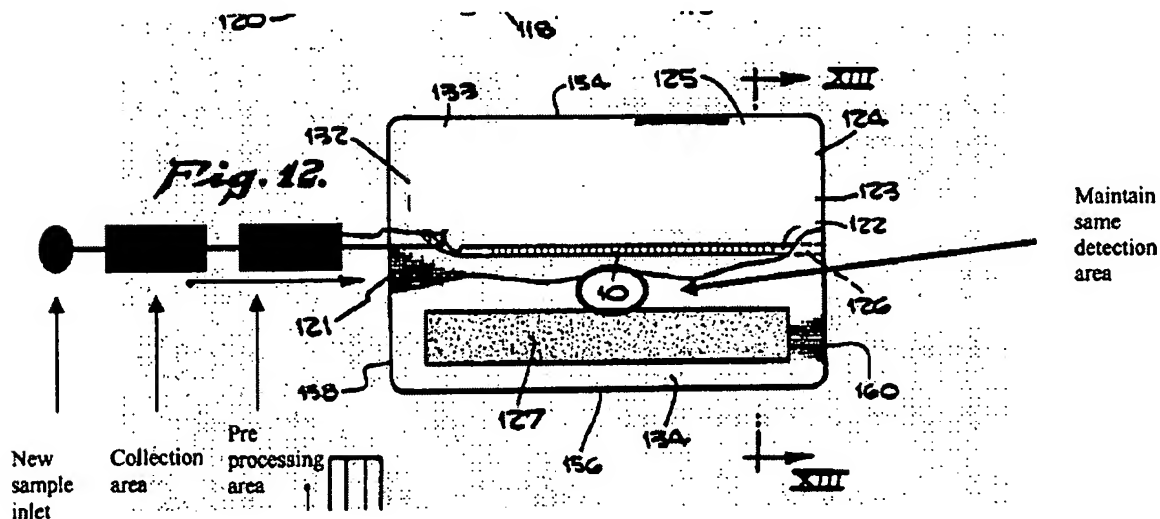
In short, Appellants respectfully submit that the statement that a “series” arrangement—rather than a hybrid “parallel/series” arrangement—has always been advanced by the Examiner, is inaccurate. In the Examiner’s Answer, the following illustration is provided, where the wash chambers 123 and 125 and solution chamber 124 of Christian are deleted:



The Examiner is now of the position that it would have been obvious to remove the “obsolete and unnecessary” chambers to provide for a “series” arrangement. Appellants respectfully submit that this is either a new ground of rejection, or a re-cycling of the grounds of rejection in the August 1, 2006 Office Action, which was subsequently withdrawn by the Examiner. For at least the reasons discussed in the Appeal Brief, the Examiner’s previous rejection relying on a hybrid “parallel/series” configuration should be withdrawn. Below, Appellants discuss why the Examiner’s newly raised rejection relying on a hybrid “parallel/series” configuration should be withdrawn.

II. The proposed modification of cited art in the Examiner's Answer changes the principle of operation from a "parallel" device to a "series" device, Christian teaches away from the proposed modification, and the proposed modification renders the device of Christian unsuitable for its intended purpose.

As discussed above, the Examiner now revises his position by stating that the proposed modification should instead be illustrated by the following diagram:



The Examiner states that this illustration serves to "better show that the preexisting buffer chambers of Christian become obsolete and unnecessary due to the addition of upstream collection and preprocessing areas." Examiner's Answer, page 14, lines 1-2. It appears that the Examiner acknowledges that this would change the principle of operation from a "parallel" device to a "series" device, but argues that such a finding of a change in a principle of operation is not a bar to finding obviousness. The Examiner alleges that in order for a change in the principle of operation to lead to a finding of non-obviousness, there must also be a teaching away from the proposed change.

The Examiner alleges that *In re Dilnot* stands for the proposition that a change in a principle of operation is not a bar to finding obviousness. Specifically, citing *Dilnot*, the Examiner states that in this case “the court as [*sic*] previous found that it is obvious to change the principle of operation from a batch process to a continuous process.” In *Dilnot*, the Court held that it was well within the skill of one having ordinary skill in the art to operate a process continuously, rather than in a batch process. The Court in *Dilnot* does not state that the change from a batch process to a continuous process is a change in the principle of operation. Therefore, *Dilnot* is irrelevant to the pending rejection. The Examiner appears to be of the position that *Dilnot* stands for a case where a change in a principle of operation was made, but such a change was insufficient to render the claims non-obvious. *Dilnot* contains no such discussion, and the allegation that the change from a batch process to a continuous process is a change in the principle of operation is merely the interpretation of the Examiner, not the holding of the Court.

With respect to *In re Ratti*, the Examiner opines that in *Ratti*, the reason for the Court’s holding of non-obviousness was not due to the change in principle of operation, but rather due to a teaching away from the proposed modification. The Examiner alleges that “Christian does not teach away from a series processing since Christian is entirely silent on that topic.” Examiner’s Answer, page 16, lines 13-14. Appellants respectfully disagree for at least the reasons discussed below.

Christian teaches away from the proposed modification. In Christian, solutions are transferred to a detection area selectively. This allows the user to precisely control the durations

of and sequence of various reactions and washing steps which take place in a complex analysis.

Christian explains as follows:

For more complicated analysis procedures in which one or more reagents are necessary to treat the microassay rod in a number of sequential steps, the microassay card in accordance with the present invention includes various raised channel portions in the top plate which are closed off by the pressure bar or rod as it moves across the card top. The raised channel portions provide a particularly convenient and simple means for programming the addition of reagents, buffer solutions and other liquids at selected intervals and in a selected sequence. Column 4, lines 37-47 (emphasis added).

In order to do this, Christian discloses that “[t]he roller 130 provides means for selectively transferring reagent, sample and wash solutions by peristaltic action into and out of the reaction zone defined by channel 122.” Column 12, lines 68 to column 13, lines 4 (emphasis added). As discussed above, this allows for a precise control of the reactions and washing of various reagents.

If Christian were modified as proposed by the Examiner, all reagent, sample and wash solutions would be mixed together before entering a reaction area. Christian specifically teaches away from this as a desired result. Christian states that:

For the most part, the present immunoassay systems utilize a single solid support coated with a single known antigen or antibody. The solid support is then used to probe one or more samples for a single immunoreactive substance (i.e., antigen or antibody). When screening a test solution for more than one antigen or antibody, the test solution must be separated to provide separate aliquots for testing. This type of screening procedure is especially undesirable where a large number of antigens or antibodies are being tested for and where the amount of test solution available is small. Column 2, lines 7-17.

In the modified device as proposed by the Examiner, if a user desired to screen a test solution for more than one antigen or antibody, the user would have to divide the test solution in multiple

parts, and test one at a time. As explained by Christian, this is undesirable and inefficient, and lacks the benefits in quantitation and detection of false positives and false negatives that comes as a result of the microarray card of Christian. See column 13, lines 44-68.

In the Examiner's Answer, the Examiner explains the alleged merits of adding a pre-processing chamber upstream of the detection chamber. See page 14, line 11 to page 15, line 7. However, even if, *arguendo*, the Examiner's comments with respect to the alleged merits of adding a pre-processing chamber upstream of the detection chamber are accurate, this ignores the fact that, due to the change in principle of operation from a "parallel" device to a "series" device, the proposed modification changes the microarray chip of Christian from a microarray chip which is able to screen a test solution for multiple antigens or antibodies to a microarray chip which is only able to screen a test solution for a single antigen at a time.

Additionally, the proposed modification renders the microarray chip of Christian unsatisfactory for its intended use—screening of a test solution for multiple antigens or antibodies at one time. As discussed above, Christian aims to screen a single solution for multiple antigens or antibodies at one time, in order to increase convenience, aid in quantitation and detect false negatives and false positives. If the microarray chip were modified as proposed by the Examiner—removing all chambers except the detection chamber—none of this would be possible. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

In summary, Appellants respectfully submit that the proposed modification of Christian illustrated in the Examiner's Answer illustrates the fact (i) that the proposed modification changes the principle of operation of the device from a "parallel" device to a "series" device, (ii) that Christian teaches away from the proposed modification, and (iii) that the proposed modification would render the microarray chip of Christian unsatisfactory for its intended use. Therefore, for at least the reasons discussed above, and in the Appeal Brief, Appellants respectfully submit that the pending rejection should be withdrawn.

III. Lack of a case of *prima facie* obviousness.

For at least the reasons discussed above, Appellants respectfully submit that the proposed modification of cited art would change the principle of operation of Christian, and thus, according to *Ratti*, the teachings of the references are not sufficient to render the claims *prima facie* obvious.

However, puzzlingly, the Examiner states that "[i]t is important to remember that the rejection does not rely on a *prima facie* case of obviousness – in fact, *four* reference, [sic] each supplying ample motivation, have been cited as evidence that a series configuration is obvious." Examiner's Answer, page 15, lines 16-18. If the rejection does not rely on a case of *prima facie* obviousness, it is unclear what the rejection relies upon, since *prima facie* obviousness is baseline requirement for all rejections based on 35 U.S.C. §103. Section 2142 of the MPEP, which discusses the legal concept of *prima facie* obviousness, is reproduced below:

The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), *amended*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to render obvious the claimed invention.

As such, Appellants respectfully submit that since a *prima facie* case of obviousness has not been established and since the Examiner admittedly does not rely on a *prima facie* case of obviousness, the rejection is both substantively and procedurally improper.

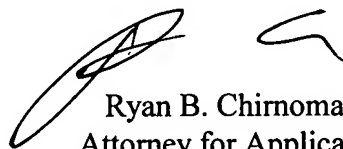
Thus, for at least the above reasons, Appellant requests that the Honorable Board reverse the Examiner's rejection.

Application No.:10/716,417
Art Unit: 1797

Reply Brief
Attorney Docket No.: 032106

If this paper is not timely filed, Appellant respectfully petitions for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,
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